The opinion in support of the decision being entered today was **not** written for publication and is **not** binding precedent of the Board.

Paper No. 23

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte ROLAND JOSEPH BYDLON and DOUGLAS DAVID HANSEL

Appeal No. 2000-0652 Application No. 08/868,774

ON BRIEF

Before CALVERT, <u>Administrative Patent Judge</u>, McCANDLISH, <u>Senior Administrative Patent Judge</u>, and NASE, <u>Administrative Patent Judge</u>.

NASE, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal from the examiner's final rejection of claims 1, 4 to 12, 25, 26 and 29 to 31, which are all of the claims pending in this application.

We AFFIRM-IN-PART.

BACKGROUND

The appellants' invention relates to medication dispensing devices (specification, p. 1). A copy of the claims under appeal is set forth in the appendix to the appellants' brief.

The prior art references of record relied upon by the examiner in rejecting the appealed claims are:

Ben Moura 3,656,472 Apr.
18,1972
Balkwill 5,279,586 Jan. 18,
1994

Claims 1, 5 to 7, 9 to 12 and 29 to 31 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Ben Moura.

Claims 4 and 8 stand rejected under 35 U.S.C. § 103 as being unpatentable over Ben Moura.

Claims 25 and 26 stand rejected under 35 U.S.C. § 103 as being unpatentable over Balkwill in view of Ben Moura.

Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellants regarding the above-noted rejections, we make reference to the answer (Paper No. 17, mailed December 15, 1999) for the examiner's complete reasoning in support of the rejections, and to the brief (Paper No. 16, filed November 26, 1999) and reply brief (Paper No. 18, filed January 24, 2000) for the appellants' arguments thereagainst.

OPINION

In reaching our decision in this appeal, we have given careful consideration to the appellants' specification and claims, to the applied prior art references, and to the respective positions articulated by the appellants and the examiner. As a consequence of our review, we make the determinations which follow.

The anticipation rejection

We will not sustain the rejection of claims 1, 5 to 7, 9 to 12 and 29 to 31 under 35 U.S.C. § 102(b).

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Verdegaal Bros. Inc. v. Union Oil Co., 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir.), cert. denied, 484 U.S. 827 (1987). It is well established that an anticipation rejection cannot be predicated on an ambiguous reference. statements and drawings in a reference relied on to prove anticipation must be so clear and explicit that those skilled in the art will have no difficulty in ascertaining their meaning. See In re Turlay, 304 F.2d 893, 899, 134 USPQ 355, 360 (CCPA 1962). Furthermore, under principles of inherency, when a reference is silent about an asserted inherent characteristic, it must be clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991). As the court stated in <u>In re Oelrich</u>, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981)(quoting <u>Hansgirg v. Kemmer</u>, 102 F.2d 212, 214, 40 USPQ 665, 667 (CCPA 1939)):

Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. [Citations omitted.] If, however, the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient.

We find ourselves in agreement with the appellants' position (brief, pp. 7-10) that independent claims 1 and 29 are not anticipated by Ben Moura. In that regard, we agree with the appellants that the limitations that the gripping layer be "formed from a material that is softer than a material used to form the portion of said base covered by said gripping layer" as recited in claim 1 and the limitation that the gripping layer be "formed of a material that is softer than a material used to form the portion of the base member covered by said gripping layer" as recited in claim 29 are not met by Ben Moura.

Ben Moura discloses an instrument for parenteral penetration of a needle. As illustrated in Figures 1 to 3 the

instrument comprises essentially a body 1, a sliding tubular support 2, a container 3, a hollow needle 4, a mouthpiece 5, a propulsion spring 6 and a latch 7. Ben Moura teaches (column 2, lines 32-39) that the instrument body 1 may be formed of plastic material or of metal and, is of elongated shape and has a configuration such as to afford a convenient grip for the user. As shown in Figures 2-3, the body 1 is provided with hollowed-out portions 11 and in which the operator's fingers may be placed in order to ensure a perfect grip. The sliding support 2 is constituted by a tubular member which is capable of sliding axially within a bore 14 of the body 1. In Figure 3, the sectional view of the sliding support 2 appears to be hatched to indicate metal.

It is the position of the examiner (answer, p. 4) that
Ben Moura teaches a gripping layer of plastic (i.e., body 1)

covering a metal base (i.e., sliding support 2) and that it

would be inherent that the plastic material of body 1 would be
a softer material than the metal support 2. We do not agree.

In that regard, it is not clear from the disclosure of Ben

Moura that the missing descriptive matter (i.e., that the

plastic material of body 1 would be a softer material than the metal support 2) is necessarily present, and that it would be so recognized by persons of ordinary skill. In fact, in view of Ben Moura's specific teaching that the body 1 be either plastic or metal, it is our opinion that Ben Moura suggests that the material of body 1 have the same hardness/softness as the material of support 2. Additionally, we note that there is no evidence in the record establishing that all plastic materials are softer than all metals.

For the reasons set forth above, the examiner has failed to establish that all the limitations of claims 1 and 29 are met by Ben Moura. Accordingly, the decision of the examiner to reject independent claims 1 and 29, and claims 5 to 7, 9 to 12, 30 and 31 dependent thereon, under 35 U.S.C. § 102(b) is reversed.

The obviousness rejection of claims 4 and 8

We will not sustain the rejection of dependent claims 4 and 8 under 35 U.S.C. § 103 as being unpatentable over Ben

Moura for the reasons set forth above with respect to independent claim 1.

The obviousness rejection of claim 26

We will not sustain the rejection of claim 26 under 35 U.S.C. § 103.

The test for obviousness is what the combined teachings of the references would have suggested to one of ordinary skill in the art. See In re Young, 927 F.2d 588, 591, 18 USPQ2d 1089, 1091 (Fed. Cir. 1991) and In re Keller, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981).

We find ourselves in agreement with the appellants' position (brief, pp. 12-13) that independent claim 26 is not rendered obvious by the combined teachings of Balkwill and Ben Moura. In that regard, we agree with the appellants that the limitation that the gripping layer be "formed from a material that is softer than a material used to form the portion of said base covered by said gripping layer" as recited in claim

26 is not suggested by the combined teachings of Balkwill and Ben Moura.

The examiner's rejection (answer, pp. 5-6) of claim 26 is based on the premise that Ben Moura suggests providing Balkwill's pen with a gripping layer as claimed. We find this position of the examiner to be untenable for the reasons set forth above with respect to independent claim 1. That is, Ben Moura does not suggest a gripping layer be formed from a material that is softer than a material used to form the portion of the base covered by the gripping layer.

Accordingly, the decision of the examiner to reject claim 26 under 35 U.S.C. § 103 is reversed.

The obviousness rejection of claim 25

We sustain the rejection of claim 25 under 35 U.S.C. § 103.

Claim 25 reads as follows:

A medication delivery apparatus comprising:

a housing elongated in an axial direction, said housing comprising a housing exterior periphery and a length extending between forward and rearward axial ends;

a container of medication mounted to said housing; an outlet in flow communication with said container to receive medication forced therefrom;

a drive assembly comprising an actuator, said actuator advanceable toward said housing in said axial direction from a first position beyond said rearward axial end of said housing to a second position to deliver a dosed quantity of medication, said drive assembly operatively connected with said container to force said dosed quantity of medication therefrom and through said outlet upon movement of said actuator from said first position to said second position; said housing exterior periphery comprising a projecting abutment for digit engagement, said abutment comprising an ergonomically curved surface axially arranged along said housing length for abutting contact by a first digit of a hand of a user when said housing is grasped within the hand of the user such that a second digit of the hand of the user may operate said actuator, whereby abutting contact of the first digit with said abutment permits application of a generally axial force by the first digit on said abutment in a direction generally opposite to an axial force applied to said actuator during advancement of said actuator from said first position to said second position; and

a dosage member operable to control said dosed quantity of medication delivered by said drive assembly.

Balkwill discloses an injection device 10 for injecting insulin or other medication. As shown in Figures 1-3, the device includes an adjusting knob 12, an upper body 14, a center body 16, and a transparent housing 18. All of these

elements have a generally cylindrical configuration, and are arranged coaxially to define a generally cylindrical housing 20 which can easily be handled by a patient or medical attendant. As shown in Figures 1, 5b and 7-9, a plunger 22 is at least partially positioned within the portion of the injection device housing 20 defined by the adjusting knob 12, upper body 14 and center body 16. The plunger includes a hollow, substantially cylindrical body 22a including a band of radially projecting ribs 22b extending outwardly therefrom. A pair of opposing projections 22c extend radially inwardly from the front end of the cylindrical body. The rear end of the plunger includes a pair of projections 22d which extend radially outwardly from the cylindrical body 22a. The rear end of the plunger 22 is secured to a push button 24. The push button fits partially within the adjusting knob 12 when the plunger is fully inserted within the injection device housing 20.

Balkwill's transparent housing 18 receives a cartridge 46 of the type including an internal piston 46b and a pierceable seal 46a at one end thereof. Both ends of the transparent

housing are threaded. One threaded end 18a is employed for connecting it to the center body 16. The other threaded end 18b is employed

for securing a double ended needle assembly 50. Needle assembly 50 includes a cannula 50a having a sharp distal end 50b for piercing the skin of the user and a sharp proximal end 50c for piercing seal 46a of the cartridge and a lumen (not shown) therethrough. Needle assembly 50 includes a cup shaped hub 50d holding said cannula so that the sharp proximal end projects outwardly from the interior of the cup-shaped hub. The cup-shaped hub includes an internal thread which is compatible with the thread at 18a so that the needle assembly may be removably attached to housing 18 with its sharp proximal end piercing pierceable seal 46a to establish fluid communication between said lumen and the interior of said cartridge.

The pertinent teachings of Ben Moura have been set forth previously in our discussion of the anticipation rejection.

After the scope and content of the prior art are determined, the differences between the prior art and the claims at issue are to be ascertained. Graham v. John Deere Co., 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966).

Based on our analysis and review of Balkwill and claim 25, it is our opinion that the only difference is the limitation that the housing exterior periphery comprises

a projecting abutment for digit engagement, said abutment comprising an ergonomically curved surface axially arranged along said housing length for abutting contact by a first digit of a hand of a user when said housing is grasped within the hand of the user such that a second digit of the hand of the user may operate said actuator, whereby abutting contact of the first digit with said abutment permits application of a generally axial force by the first digit on said abutment in a direction generally opposite to an axial force applied to said actuator during advancement of said actuator from said first position to said second position.

In applying the above-noted test for obviousness, we reach the conclusion that it would have been obvious at the time the invention was made to a person of ordinary skill in the art to provide the outer surface of Balkwill's housing 20 with a configuration as taught and suggested by Ben Moura's

body 1 having an outer surface with hollowed-out portions so that the operator's fingers may be placed therein in order to ensure a perfect grip as taught by Ben Moura.

The appellants' argument (brief, pp. 10-14; reply brief, p. 3) that the rejection of claim 25 under 35 U.S.C. § 103 is in error is not persuasive for the reasons that follow.

First, for the reasons set forth above, it is our view that the combined teachings of the applied prior art are suggestive of the claimed invention without the use impermissible hindsight. In that regard, Ben Moura clearly teaches to provide the outer surface of body 1 with hollowed-out portions 11 so that the operator's fingers may be placed therein in order to ensure a perfect grip. It is this teaching of Ben Moura that provides the required motivation and suggestion to a person of ordinary skill in the art to have modified Balkwill's device in the manner set forth above.

Second, the appellants have noted the deficiencies of each reference on an individual basis, however, it is well-settled that nonobviousness cannot be established by attacking the references individually when the rejection is predicated upon a combination of prior art disclosures. See In re Merck & Co. Inc., 800 F.2d 1091, 1097, 231 USPQ 375, 380 (Fed. Cir. 1986).

Lastly, the appellants point out that the patent to Ben Moura issued in 1972 and that Balkwill's patent application was filed in 1992. The appellants appear to argue that the fact that Balkwill did not incorporate the teachings of Ben Moura into his device is evidence of nonobviousness. This argument is without merit. Any "failure" of Balkwill to incorporate the teachings of Ben Moura in his own apparatus is not evidence of nonobviousness in this case because the evidence in this record neither shows that Balkwill actually knew of the patent to Ben Moura nor that he was seeking to solve a problem that is solved by the appellants' invention.

See In re Touvay, 435 F.2d 1342, 1344, 168 USPQ 357, 359 (CCPA 1971).

For the reasons set forth above, the decision of the examiner to reject claim 25 under 35 U.S.C. § 103 is affirmed.

CONCLUSION

To summarize, the decision of the examiner to reject claims 1, 5 to 7, 9 to 12 and 29 to 31 under 35 U.S.C. § 102(b) is reversed; the decision of the examiner to reject claim 25 under 35 U.S.C. § 103 is affirmed; and the decision of the examiner to reject claims 4, 8 and 26 under 35 U.S.C. § 103 is reversed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR $\S 1.136(a)$.

AFFIRMED-IN-PART

IAN A. CALVERT)	
Administrative Patent Judge)	
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)	BOARD OF PATENT
HARRISON E. McCANDLISH)	APPEALS
Senior Administrative Patent Judge		
) AND	,	
)	INTERFERENCES
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JEFFREY V. NASE)	
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